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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,825

01/06/2006

Vincent Saldell

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,825	Applicant(s) SALDELL, VINCENT	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-3-2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 4/3/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

35 U.S.C. 112 6th Paragraph

1. In reference to claims 1, the Examiner notes that the Applicant may be intending to invoke 35 U.S.C. 112 6th paragraph by using "means for" language reciting function, and not reciting sufficient structure of the means referred to in the specification.
2. Specifically, in claim 1, the Applicant's recitation of limitations: "holding means for" in lines 4 and "holder means for" in ln 19 respectively may invoke 35 U.S.C. 112 6th paragraph by using "means for" language reciting function, and not reciting sufficient structure of the means referred to in the specification.
3. The Examiner notes that if the Applicant intends to invoke 35 U.S.C. 112 6th paragraph the Applicant needs to state that on the record and include a specific and detailed description and citation of the exact structure in the specification the means for language is invoking.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "holding means for" in lns 4 and "holder means for" a first and second part respectively. It is unclear the meaning of these limitations and further if "holder means for" is a separate element or meant to reference "holding means for". Appropriate clarification and correction is required.

5. Claim 1 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "said axes are essentially parallel and *sufficiently rigid*" (emphasis added) in ln 13. A single axis, or two axes as claimed, cannot be rigid. An axis is a straight line about which an element may rotate. It has no physical embodiment. Thus, it cannot be claimed as sufficiently rigid.

6. Claim 1 recites the limitation "the needle" in ln 6; "the joint axes" in ln 15; "the user" in ln 16; "the needlestick" in ln 18; and "the patient" in ln 18. There is insufficient antecedent basis for these limitations in the claim.

7. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites "the holding means is separate from the first part". However, claim 1 reads "the first part including a holding means for" in lns 3-4. Thus, it appears the holding means cannot be claimed separate from the first part in

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claim 3. Additionally, the examiner is unsure why In 4 of claim 3 recites “(second) joint device”. The use of a parenthetical is confusing.

8. Claim 9 recites the limitation "the capillary force" in In 2. There is insufficient antecedent basis for these limitations in the claim.

9. Regarding claim 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. Regarding claim 11, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Claim 14 recites the limitation "the joint device" in In 2. There is insufficient antecedent basis for these limitations in the claim.

Claim Objections

12. Claim 18 objected to because of the following informalities: Claim 18 recites “fixing means” which is recited in claim 17 but not claim 1. However, claim 18 depends from claim 1. The examiner believes claim 18 should depend from claim 17.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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14. Claims 1-6, 9-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al (4867172). Haber et al discloses a device for protection of a needle (14) for a medical device that includes a first part (8-1) and a second part (8-2), which are movably connected, the first part including a holding means for retaining the medical device (2; Figs 1-10), so that the two parts can be brought together to a first position (Fig 10) for enclosing the needle and can be separated from each other to a second position (Fig 9) where a retained needle is in a free position, characterised in that the first part is pivotally connected about an axis (near 20) to the holding means, the second part is pivotally connected about an axis (10) to the first part at a distance from the holding means, the needle only can describe a plane that is perpendicular to the joint axes (needle 14 is perpendicular to 10 and 20), whereby the two parts are capable of protecting the user from the tip of the needle in directions facing the user before, during and after the needlestick on the patient (Figs 1-10), and the second part includes a holder means for fixing said second part (22).

15. Furthermore, Haber et al discloses a recess (area between 8-1 and 8-2 holding needle in Fig 10) complementary to the needle, the holding means having a recess (2; Figs 1-10) and fitted with a mechanism being either a snap lock device or screw device (syringe fits within 2 by snaps); a means (20) to limit an angle between the first and second parts and an angle between the first part and needle; the recess designed to absorb blood (recess between 8-1 and 8-2 in Fig 10 encloses needle to prevent leakage; wherein the examiner notes that "by the capillary force" is a product-by-process limitation see MPEP 2113); the second part has a end part for application on a

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patient with a frictional or adhesive surface (8-2 has a fictional outer surface fully capable of engaging the patient - Figs 11-17 showing use); the second part being reinforced with a penetration protection (10); a locking mechanism (22); an injection syringe (Figs 1-10); a handle (4).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. Habet er al discloses the invention substantially as claimed except for expressly disclosing angles between the first and second parts being between 30-60 degrees and angles between first part and needle being 50-80 degrees. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have angles between the first and second parts being between 30-60 degrees and angles between first part and needle being 50-80 degrees because the Applicant has not disclosed that having angles between the first and second parts being between 30-60 degrees and angles between first part and needle being 50-80 degrees provides an advantage, is used for a particular purpose, or solves a stated problem. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation. See MPEP 2144.05 and *In re Aller*, 220 F.2d 454, 4566, 105 USPQ 223, 225 (CCPA 1955).

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 Form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767